

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2000 list were published in the Federal Register in January 2000

New Approvals

NADA Number: 140-863

Trade Name: Paylean®
Ingredients: Ractopamine hydrochloride
Sponsor: Elanco Animal Health
Approval Date: December 22, 1999
Status: Over-the-counter
Route: Oral
Species: Swine (finishing)
Drug Form: Type A Medicated Article to make Type B and Type C medicated feeds.
Concentration: 9 grams per pound of Type A Medicated Article
Indications: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine.
Tolerance: 21CFR 556.570: An acceptable daily intake (ADI) for total residues of ractopamine is 1.25 micrograms per kilogram of body weight per day. A marker residue tolerance is established for ractopamine hydrochloride parent of 0.15 ppm in liver, the target tissue, and a muscle tolerance of 0.05 ppm.
Withdrawal: Zero days
Patent Number: 4,690,951 Expiration date: September 1, 2004
 4,734,437 September 1, 2004
Exclusivity: 5 years

21CFR 556.570 and 558.500 (FR 1/26/00, page 4111)

Suitability Petition Action

Number: 99P-2733/PRC 1
Sponsor: Wildlife Laboratories, Inc.
Petition: Request permission for reconsideration to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: The generic product will provide for a product containing 200 mg/mL ketamine hydrochloride whereas the pioneer product contains 100 mg/mL ketamine hydrochloride.
Action: Filed on December 10, 1999

Number: 00P-0117/CP 1
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, lincomycin hydrochloride and spectinomycin sulfate pentahydrate, which differs from the pioneer product, Pharmacia & Upjohn Co., NADA 046-109 by the following characteristics: The generic product will provide for a product containing spectinomycin sulfate pentahydrate whereas the pioneer product contains spectinomycin sulfate tetrahydrate.
Action: Filed on January 10, 2000

Correction of a Patent Number

NADA Number: 141-123

Patent Number: 4,255,431 Expiration Date: April 5, 2001